DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

94980d

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: FEI 3002771167

September 15, 2004

Darrel J. Plimpton, President
John E. Andrick, Director
Nagasako Fish Ltd.
800 Eha Street, Units 11 & 12
Wailuku, Hawaii 96793

WARNING LETTER

Dear Messrs. Plimpton and Andrick:

On April 20 and 21, 2004, we inspected your seafood processing facility located at 800 Eha Street, Units 11 & 12, and Wailuku, Hawaii. We found that you have serious deviations from Title 21 of the Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fish and fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna, Mahi Mahi, Wahoo, and Escolar are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Food and Drug Administration's (FDA) Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 through links in FDA's home page at www.fda.gov. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious deviations were as follows:

1. You must have a HACCP plan that at a minimum lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for "Fresh Fish: dressed, loined, histamine Forming fish species, aku, ahi, kajiki, nairagi, mahimahi, ono, papio, akule, opelu, uku, lehi, white ula, butaguchi, omilu" lists the critical limits "1) Internal temperature of fish not to exceed [redacted] F and 2) No evidence of extensive decomposition" at the "Receiving" critical control point (CCP). These critical limits are not adequate to control histamine formation in histamine forming fish.

Our investigator observed that your firm is both a primary and secondary processor in that you receive fish directly from fishermen and also from intermediary purchasers.

As a primary processor who receives fish directly from the harvesters or harvest vessels, in addition to your listed critical limit of an internal temperature of [redacted] degrees F or less, your HACCP plan should include a critical limit either requiring harvest vessel records or conducting histamine testing on a representative sample of fish. In addition, your plan lists critical limit of "no evidence of extensive decomposition" that is insufficient. FDA currently recommends that a lot of fish be rejected or undergo histamine testing if 2.5% or more of the fish in the sample exhibit characteristics of decomposition. Decomposition should be determined on a pass/fail basis.

As a secondary processor that receives fish that have been transported longer than 4 hours, your plan should also include a critical limit to assure that safe temperatures were maintained throughout transportation. FDA recommends either checking the adequacy of cooling media at receipt or another assurance that the product was adequately cooled during transit such as requiring time/temperature data loggers during transport.

The recommended controls necessary for receiving fish from the harvester differ from the recommended controls for receiving fish from another processor. You may refer to Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance for examples of adequate critical limits and monitoring procedures/frequencies for both histamine testing and harvest vessel records.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for "Fresh Fish: dressed, loined, histamine Forming fish species, aku, ahi, kajiki, nairagi, mahimahi, ono, papio, akule, opelu, uku, lehi, white ula, butaguchi, omilu" lists a monitoring frequency of "single sample of every delivery" at the "Receiving" critical control point that is not adequate to control histamine formation resulting from time/temperature abuse for product received directly from harvest vessels. FDA recommends a minimum of 12 fish be monitored for internal temperature when received from harvest vessels.

3. You must implement the record keeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving" critical control point listed in your HACCP plan for "Fresh Fish: dressed, loined, histamine Forming fish species, aku, ahi, kajiki, nairagi, mahimahi, ono, papio, akule, opelu, uku, lehi, white ula, butaguchi, omilu." Our investigator reviewed your receiving records for the months of February and March 2004. Your firm failed to record monitoring observations for temperature and decomposition for most of the shipments received during this time.

4. Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b).

    (a) However, your corrective action plan for "Fresh Fish: dressed, loined, histamine Forming fish species, aku, ahi, kajiki, nairagi, mahimahi, ono, papio, akule, opelu, uku, lehi, white ula, butaguchi, omilu" contains a corrective action at the "Receiving" critical control point "Reject decomposed fish based on sensory evaluation," that is not adequate to control histamine formation. While rejecting individual decomposed fish is appropriate it is not adequate to ensure that the remaining portions of the affected lot are acceptable and safe for distribution into commerce. FDA recommends that you either reject the entire lot or perform histamine analysis to determine product safety and disposition of potentially hazardous product. In addition, FDA also recommends discontinuing use of the supplier or carrier unless you obtain information that transportation practices have improved to correct the deviation.

    (b) Furthermore, your corrective action plan for "Fresh Fish: dressed, loined, histamine Forming fish species, aku, ahi, kajiki, nairagi, mahimahi, ono, papio, akule, opelu, uku, lehi, white ula, butaguchi, omilu" contains a corrective action at the "Cold Storage" critical control point "Reject if excessively decomposed," that is not adequate to control histamine formation. As mentioned above in item 5(a), rejecting only the decomposed portions of the lot does not ensure the acceptability and safety of the remaining product. In addition to determining the safety of the affected product, FDA also recommends that your corrective action plan include provisions for correcting the cause of the deviation.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, based on our observations, your firm did not monitor the following key sanitation areas with sufficient frequency to ensure control of:

    a. Condition and cleanliness of food contact surfaces – [redacted] shelving used to store fresh fish loins contained a heavy build up of old and dried fish matter; one fresh tuna loin was placed directly on the dirty wire rack shelving;

    b. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces – tuna and marlin were stored directly on the floor of the cooler storage; marlin was dragged through the bloody water and pushed along with the employee's rubber

boot before placing the fish on top of the wire storage rack; the fan guards located directly above the filleting and weighing tables contained a heavy build up of filth.

c. Proper storage of toxic compounds – The [redacted] degreaser and the [redacted] Sanitizer stored in the cooler storage area near exposed seafood product.

6. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records since February 18, 2004.

You must immediately take appropriate steps to correct the violations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

for Barbara J. Cassens
District Director
San Francisco District